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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,071	09/13/2005	Pascal Bernard	0579-1082	5118
<div>466 7590 05/23/2008</div> <div>YOUNG &amp; THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314</div>			<div>EXAMINER</div> <div>MARCETICH, ADAM M</div>	
			<div>ART UNIT</div> <div>3761</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>05/23/2008</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/520,071

**Applicant(s)**

BERNARD ET AL.

**Examiner**

Adam Marcetich

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. France 0208467, filed on 05 July 2002 has been received.

### ***Claim Rejections - 35 USC § 102 / 103***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

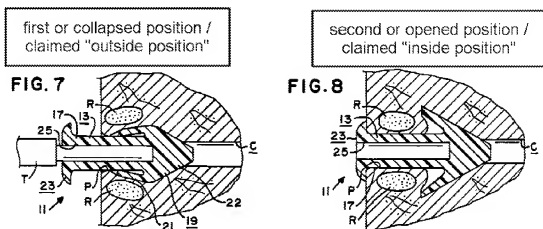
5. Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace (US Patent 5,830,171).

6. Regarding claim 1, Wallace discloses a punctal occluder (column 2, lines 29-37) adaptable for use as a meatal occluder of a human eye, comprising:

a substantially cylindrical body (column 3, lines 50-54 and Figs. 1-3, shank 13) characterized in that it further comprises:

at least one fin adapted to take up an outside position outside the lachrymal meatus wherein the fin is substantially folded into the cylindrical body (column 3, lines 55-64, especially lines 60-61 and Fig. 7, wing portion 21 having a first collapsed position, see annotated figure below. Regarding the limitation of being outside the lachrymal meatus, it is the Examiner's position that wing portion 21 of Wallace may be placed within a different physiological lumen, or held in its folded position manually or by deployment means.); and

an inside position into the lachrymal meatus wherein the fin projects from the cylindrical body (column 3, lines 64-67, especially lines 64-65 and Fig. 8, wing portion 21 having second expanded position, see annotated figure below).



Annotated Figs. 7, 8 of Wallace

Examiner notes that Wallace uses the same material, silicone (column 5, lines 8-13) as disclosed in the immediate specification (p. 8, lines 1-5, especially line 2), therefore the material used by Wallace is fully capable of being heat-deformable as claimed [claim 1].

7. Regarding claims 2 and 3, Wallace discloses a meatal occluder characterized in that it is made from silicone (column 5, lines 8-13). Examiner notes that silicone is a heat-expandable material, since it is capable of expanding when heated. In other words, the language "heat-expandable" is being interpreted to include materials that expand when heated, such as silicone.

When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, a substantially cylindrical body and at least one fin of

Wallace as discussed) except for a property or function (in the present case, said fin being heat-deformable from said outside position to said inside position, and the implant being made from a heat-expandable material) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

8. Regarding claim 4, Wallace discloses the invention as substantially claimed. See above. Wallace discloses an implant comprising silicone as discussed above. The specification of the immediate application discloses silicone as a polymer capable of having a vitreous transition temperature from -10°C to 30° (page 8, lines 11-15). Therefore, the property of vitreous transition temperature is an intrinsic property of the materials used, and the device of Wallace is capable of having a vitreous transition temperature from -10°C to 30°C.

9. Regarding claim 5, Wallace discloses a meatal occluder characterized in that said fin pivots between said folded position and said extended position about an axis perpendicular to a longitudinal plane of said meatal occluder (column 4, lines 35-42 and Figs. 7 and 9, wing portion 21 pivoting about axis perpendicular to longitudinal plane of shank 13).

10. Regarding claim 6, Wallace depicts a meatal occluder characterized in that said fin when in said folded position extends in a direction substantially parallel to the longitudinal direction of the cylindrical body (Fig. 7, wing portion 21 extending substantially parallel to shank 13).

11. Regarding claim 7, Wallace depicts a meatal occluder characterized in that said fin is situated in the vicinity of one end of said cylindrical body, a free end of said fin, when in the folded position, extending in the direction of the opposite end of said cylindrical body (Fig. 9, end of wing portion 21 having folded position extending in direction opposite of shank 13).
12. Regarding claim 9, Wallace discloses a meatal occluder characterized in that said fin is situated in the vicinity of a tapered end of said cylindrical body, the opposite end of said cylindrical body comprising a flange (column 4, lines 22-24 and 43-49; Figs. 2 and 3, flange 23 near nose portion 22).
13. Regarding claim 10, Wallace discloses a meatal occluder characterized in that it comprises a plurality of fins regularly distributed on the cylindrical body of said occluder (column 4, lines 22-24, "wing portion 21 may be formed by a plurality of individual wing elements").

***Claim Rejections - 35 USC § 103***

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent 5,830,171) in view of Zhou et al. (US Patent 6,234,175).
15. Regarding claim 11, Wallace discloses a punctal occluder (column 2, lines 29-37), adaptable for use as a meatal occluder of a human eye, comprising:  
a substantially cylindrical body having a longitudinal axis (see discussion of claim 1 above);

at least one fin comprising a heat-deformable material (see discussion of claim 1 above, especially section on heat-expandable material); and

the at least one fin being positioned to extend from the cylindrical body substantially parallel to the longitudinal axis (Fig. 7, wing portion 21 having a first collapsed position substantially parallel to longitudinal axis).

16. Wallace discloses the invention as substantially claimed, see above. However, Wallace lacks a fin positioned to extend as claimed [claim 11]. Zhou discloses an ocular plug comprising a fin and being made of materials that adapt to an individual's punctum or canaliculus through material properties (col. 1, lines 11-19, especially lines 15-19). Zhou also discloses a silicon material (col. 3, lines 39-44, especially line 43). Zhou discloses a fin positioned to extend and expand upon exposure to a heating effect of the human body (Figs. 2 and 9, left side of figures). Zhou provides the advantage of more closely matching an individuals' physiology to prevent an ocular plug from being dislodged during use. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wallace as discussed with the heat-expanding effect as taught by Zhou in order to prevent an ocular plug from dislodging.

17. Regarding claims 12, 13, 14, 15, 16, 18 and 19, see discussion of claims 2, 3, 4, 5, 7, 9 and 10 above, respectively.

18. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent 5,830,171) in view of Fouere (US Patent 6,254,562).

19. Regarding claim 8, Wallace in view of Zhou discloses the invention as substantially claimed. See above. However, Wallace in view of Zhou lacks a fin pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of a cylindrical body as claimed [claim 8]. Fouere discloses a meatal occluder having fins pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of the cylindrical body (column 2, lines 50-56; Fig. 2, gripping means 12). Fouere provides the advantage of preventing involuntary expulsion of a meatal occluder (column 1, lines 59-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wallace in view of Zhou as discussed with the pivoting fins as taught by Fouere in order to prevent involuntary expulsion of a meatal occluder.

20. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent 5,830,171) in view of Zhou et al. (US Patent 6,234,175), further in view of Fouere (US Patent 6,254,562).

21. Regarding claim 17, Wallace in view of Zhou discloses the invention as substantially claimed. See above. However, Wallace in view of Zhou lacks a fin pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of a cylindrical body as claimed [claim 17]. Regarding rationale and motivation, see discussion of claim 8 above.

***Response to Arguments***

22. Applicant's arguments filed 28 January 2008 have been fully considered but they are not persuasive.
23. Applicant asserts that there is no condition or time in the Wallace device at which the device is outside the lachrymal meatus and having a position in which the fin is substantially folded into the cylindrical body, since it is only upon the insertion of the device into the punctal ring R that the fins are deflected into position in which they are nearer the cylindrical body. Examiner notes that the claims are drawn to a device, not a method of using. Examiner also notes that the limitation of being "outside the lachrymal meatus" is interpreted broadly to include holding the implant manually or with insertion means.
24. Applicant asserts that the newly added claims define the structure, arrangement and composition so as to define a cause and effect relationship between two different positions of the fin with respect to the cylindrical body and a temperature to which the device is exposed. Applicants respectfully suggest that there is no reasonable way to interpret the Wallace reference in such a way as there to be any doubt as to whether the device disclosed therein might inherently possess the particular recited properties. Examiner notes that Wallace discloses the same claimed structures (a cylindrical body and at least one fin) the same claimed arrangement (the fin adapted to be folded substantially parallel to the cylindrical body), and the same claimed composition (silicone polymer). Therefore, a rejection based on inherency is proper.

25. Applicant correctly asserts that the additional Fouere reference is offered merely for its asserted description of a fin pivoting between the folded position and an extended position about an axis parallel to the longitudinal direction of the cylindrical body and fails to overcome the shortcomings of the primary Wallace reference. Examiner notes that Wallace is relied upon for the limitations of the claimed structures, arrangement and compositions as claimed.

### ***Conclusion***

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-

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2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761